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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,270	09/24/2003	Peter A. Altman	212/511	3869

23371 7590 09/28/2010

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EXAMINER	
CHENG, JACQUELINE	
ART UNIT	PAPER NUMBER
3768	
MAIL DATE	DELIVERY MODE
09/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/671,270	ALTMAN ET AL.	
	Examiner	Art Unit	
	JACQUELINE CHENG	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-14,16-24,26-34 and 36-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-14,16-24,26-34 and 36-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/1/10, 7/20/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed July 2, 2010 have been fully considered but they are not persuasive. The examiner respectfully disagrees with the applicant's arguments that Nash (US 6,709,427) in view of Stegmann (US 2002/0122792) does not teach the invention as claimed, in particular that the injection of the agent is at a location distal to the stent, site of angioplasty, or diseased segment of the coronary blood vessel. Stegmann discloses injecting an agent to the myocardium at or near the site of coronary artery stenosis. The examiner believes that it is obvious that the injecting "near the site of coronary artery stenosis" includes an injection "at a site distal to the coronary artery stenosis" (the coronary artery stenosis being the diseased segment, where the site of angioplasty or stenting would be done) as the site distal to the coronary artery stenosis is a site near the site of the coronary artery stenosis. Furthermore the examiner believes that a site distal to the stent, site of angioplasty, or diseased segment of the coronary blood vessel, does not have to be a site downstream, it only has to be a site "situated away from the origin or a central point" (distal as defined by Merriam-Webster). Either a point upstream or downstream from the stent, site of angioplasty, or diseased segment of the coronary blood vessel are sites situated away from the origin or central point of the stent, site of angioplasty, or diseased segment of the coronary blood vessel. It is therefore believed that the previous rejections of claims 5, 15, 25, and 35 dated March 2, 2010 still stand for the newly amendment claims 1, 11, 21, and 31. New grounds of rejections have been made for dependent claims and claim 41 as necessitated by the amended independent claims.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 21, 23, 31, and 33** are rejected under 35 U.S.C. 102(e) as being anticipated by Stevens (US 6,152,141). Stevens teaches a method of delivery of therapeutic agents to the heart by injecting an agent directly into the myocardium by inserting a catheter into the coronary artery and piercing the wall of the coronary artery (col. 8 line 37-40, fig. 9) (which would be through the vessel wall into a peri-adventitial layer) to treat intraluminal diseases such as a stenosis (fig. 10b element 102) at a site distal to the segment (fig. 10b). Stevens discloses that the agent can be any type of drug or agent such as VEGF (abstract) which is an anti-restenosis agent (see US 5,961,459 to Kaul which specifically states that VEGF is an anti-restenosis agent in col. 6 line 41-47).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 24, 26-38, 30, 34, 26-38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens as applied to claims 21 and 31 above, and further in view of Sahatjian (US 5,843,089).

6. **Claims 26-28, 30, 36-38, 40:** Stevens discloses most of what is claimed including that the agent delivered can be any type of drug or agent (col. 2 line 38-48). It would therefore be obvious to use any well known type of drug or agent such as disclosed by Sahatjian. In the same field of endeavor of providing a therapeutic agent to an occluded region of a blood vessel Sahatjian discloses the therapeutic agent can be an anti-angiogenic drug, a nucleic acid incorporated into a liposome, or a gene therapy agent such as antisense oligonucleotides and can be incorporated into microspheres to provide a time released formulation (col. 2 line 20-45). It would be obvious to use the therapeutic agents disclosed in Sahatjian in Stevens as Stevens discloses any type of drug can be used as well as for the purpose of preventing restenosis at the stent site as taught by Sahatjian (col. 2 line 20-22).

7. **Claims 24, 34:** Stevens does not explicitly disclose piercing the coronary vein, however it is obvious to one skilled in the art to perform the injection of agent where the occlusion has occurred for the purpose of treating the stenosis. If the occlusion occurred in the coronary vein instead of the coronary artery it would be obvious to pierce the needle 527 (fig. 10a, 10b) into the coronary vein in order to treat the stenosis.

8. Claims 1-4, 6-8, 11-14, 16-18, 21-24, 26-28, 31-34, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash in view of Stegmann (US 2002/0122792 A1).

9. **Claims 1-3, 6-8, 11-13, 16-18, 21-23, 26-28, 31-33, 36-38:** Nash discloses a method of delivering agents to a targeted tissue as an adjunctive therapy in addition to other cardiac therapies such as stenting (an angioplasty procedure) (col. 17 line 19-25) comprising injecting the agent into the myocardium from an endocardial region (col. 19 line 10-14), or through the wall of the coronary artery into the myocardium (fig. 6, 8, col. 22 line 12-24) (which would be through the vessel wall into a peri-adventitial layer). Nash does not explicitly disclose from where in the endocardium or coronary artery the agent is injected to so therefore it would be obvious to one skilled in the art to inject the agent from anywhere in the endocardium or artery well known in the art depending on the region that needs to be treated. If Nash was treating a stenosis in the coronary blood vessel it would be obvious to inject the agent (such as a time released anti-restenosis gene therapy agent, adenovirus, encapsulated in microspheres, col. 30 line 66- col. 31 line 30) at a location distal to the stent or distal to the diseased location to be treated as Stegmann discloses injecting an amount of agent to the myocardium at or near (proximate) a site of a coronary artery stenosis (paragraph 0015). A location distal to the stent or diseased location to be treated is a site near or proximal a site of coronary artery stenosis. It would therefore be obvious to inject an agent at a site distal to the stent or distal to the diseased location to be treated as taught by Stegmann in Nash for the purpose of treated the diseased location.

10. **Claims 4, 14, 24, 34:** Nash discloses injecting the therapeutic agent through a wall of a coronary blood vessel into the myocardium (peri-adventitially through the blood vessel wall) (col. 21 line 43-45). It would be obvious to inject the agent into any well known coronary blood

vessels such as a coronary vein or a coronary sinus for the purpose of treating an occlusion that is in the coronary vein or coronary sinus.

11. **Claims 9, 10, 19, 20, 29, 30, 39, and 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash in view of Stegmann as applied to claims 1, 11, 21, and 31 above, and further in view of Levine (US 2002/0019350 A1). Nash and Stegmann disclose most of what is claimed including providing agents such as anti-restenosis gene therapy agents but fail to disclose how the agents were encapsulated. Levine discloses that anti-restenosis gene therapy agents can be encapsulated in micelles and/or liposomes (paragraph abstract, 0144). It would be obvious to deliver the anti-restenosis agents of Nash or Stegmann in any well known carrier vehicles such as the micelles and/or liposomes as disclosed by Levine for the purpose of having a delivery vehicle for the agents.

12. **Claim 41 is** rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens further in view of Kunz (US 5,981,568). Stevens discloses all the pieces of the kit including a needle catheter 523 (fig. 9) having a means for introducing a therapeutic agent 528 into a perivascular space surrounding the blood vessel (col. 8 line 37-39) and a dose of therapeutic agent (col. 8 line 35-36), but does not explicitly disclose a kit comprising the parts of their method or instructions to perform the method. It would be obvious to put the parts needed to perform a method in a kit as well as instructions to perform the method as this is well known in the art to do. For example, Kunz discloses not only a kit to perform a method, but also discloses in particular a kit for inhibiting restenosis comprising a catheter, a dose of therapeutic agent, and instruction means for

directing the kit's use. Since the method of Stevens comprises positioning the catheter into the desired location (such into the perivasular space at a site distal to the diseased treatment region) and delivering the dose to where the catheter is placed, it would be obvious that the instructions would state this.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3737

/Jacqueline Cheng/
Examiner, Art Unit 3768